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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,725	11/09/2001	Bo Skaaning Jensen	2815-0183P	5880

2292 7590 10/25/2002

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EXAMINER	
FORD, JOHN M	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/966,725	Applicant(s) Jensen et al
	Examiner J. McFarlane	Group Art Unit 1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on Oct 8 2002.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1--21, 24--34 is/are pending in the application.

Of the above claim(s) 20, 21, 24, 25 and 27--32 is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1--17, 19 and 26 is/are rejected.

☒ Claim(s) 18 and 34 is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____ ☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other_____

Office Action Summary

Applicants response of Oct. 8, 2002, is noted.

The claims in the application are claims 1--21 and 24--34.

Claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraph, as applicants did not set forth the active ingredient chemical compound. Having selective Ikca modulatory activity does not tell the reader what the compound is.

Claim 21 is rejected under 35 U.S.C. 112, 1st and 2nd paragraph.

In Ar1, Ar2, and Ar3, completely saturated aryl is impossible.

The claim does not say what the aryl is. The claim does not say what they heterocyclic group is.

Same rejection, as above, in regard to R of claim 2.

The expression completely saturated -- aryl needs to be removed from claim 3 and 4 and 5 and 6 and 7 and 8, and 9 and 10 and 11 and 12 and 13.

Claims 4 and 6 and 8 and 10 and 12, rejected for the reasons claim 2 was rejected.

The expression completely saturated -- aryl needs to be removed form claims 14, 15, 16, 17.

Claim 14 is rejected for the reasons claim 2 was, as is claim 16.

Claim 18 is objected to as being an Improper Markush of unrelated compounds.

Claim 19 is rejected under 35 U.S.C. 112, 1st paragraph.

No proof of the allegations of claim 19 are noted in the specification (35 U.S.C. 101) and 112, 1st paragraph.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, the Board noting that remission, not cures, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancers, was held insufficient to establish the utility of claims directed to a method of treating seven cancers. In re Butting, (CCPA 1969) 418 F2d, 163 USPQ 689.

Claim 1 relates to a laboratory test, and does not relate to the real World of Commerce.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. V. Manson, (USC 1966) 383 US 519, 148 USPQ 689. The Court did state, however, that congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the World Commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hardtop, 135 USPQ 419 is "whether the invention has been brought to such

perfection as to be capable of practical employment." This language is echoed in Bindra vs. Kelly 206 USPQ 570.

Issentstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. of Pats. (DCDC 1967) 269.F. Supp 630, 155 USPQ 838. Noted where an application discloses therapeutic effect on human or a cure for a human disease as the utility of a claimed process, the Distinct Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev. v. Brenner, Forguson, (POBA 1957) 117 USPQ 229.

Where utility is based on the alleged enhancement of activity of known medicinals. The CCPA up held the Examiner's requirement that the applicant submit evidence which substantiated the allegation, the Court holding such requirement proper where utility is based on the type of allegation, unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F.2d 924, 134 USPQ 335.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded form finding an inference of human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease, such as cancer. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron, (CCPA 1964) 325 f2D 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F2d. 135 USPQ 419.

The agreement to consider one use of the compounds with the compounds is based on the claims being of the same scope. Claims 20, 21, 24, 25 have additional active ingredients and would, therefore, not be searched in the same subclasses as it (the search) would be controlled by the additional active ingredients and, therefore, the claims 20, 21, 24 and 25 is not of the same scope as the compound claim, and would never be considered to be recombined, as they are is not of the same scope as the earlier claim 2.

This requirement of one specific real world of Commerce utility, is also consistent with the Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, (Rule 475) and PCT, Rule 13.2.

Claim 1 does not suggest "currently available from".

Such a statement cannot be acceptable as one specific utility. The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which require that utility be developed to appoint where "specific benefits exist in currently available form. Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of in re Hartop, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practice employment. This language is echoed in Brinda vs. Kelly 206 USPQ 570.

The PTO has amended the guidelines to clarify "specific utility". The court focused on the facet that the applicant filed to identify a "Specific utility" in Brenner v. Manson.

Claims 20, 21, 24, and 25 therefore, are held withdrawn under 37 CFR 1.142(b).

Claim 19 is not limited to one specific disease, nor is claim 1.

MPEP 806.05(h) provides for restricting out altogether claims drawn to more than one method of use.

Claim 27 lists a hugh number of auto-immune diseases.

Claims 27--33 allege many valid uses, therefore, they provide the allegation that the compounds may be used for more than one purposes. Therefore, they are restrictable, and claims 27--33 stand withdrawn under 37 CFR 1.142(b).

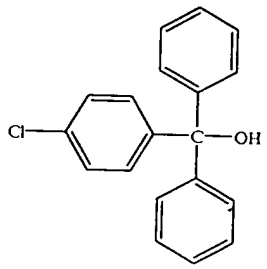
Claim 26 is rejected as it is dependent on a rejected claim.

Please expand on what claim 33 means, if it is the elected use. Written in dependent form, it is hard to understand what the wording of the complete claim is. What does treating sclerosis, mean? Ataxic sclerosis, multiple sclerosis, systemic sclerosis. See claim 19.

Claim 34 is objected to as being dependent on a rejected claim.

What is the structure of the compound of claim 34: How does it relate to claim 2?

See col. 21 of US Patent 6,028,103:



Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

John M. Ford:jmr

October 22, 2002

JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624